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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,247	07/25/2003	Sean D. Monahan	Mirus.007.01.2	4188
25032	7590	09/22/2005	EXAMINER	
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	10/627,247		MONAHAN ET AL.	
	Examiner		Art Unit	
	David Guzo		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-17, 20 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17, 20 and 24-31 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/6/05 has been entered.

### **35 USC 102 Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-17 and 24-27 and 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Soane et al.

Applicants claim a process for delivering a cargo (i.e. nucleic acids) to a cell, said method comprising inserting said cargo into a reverse micelle comprising a plurality of amphipathic molecules containing reactive functional groups and a biologically labile bond which can be a disulfide bond, polymerizing two or more of the amphipathic molecules thereby forming a polymerized reverse micelle and contacting the cell with

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the polymerized reverse micelle. Applicants also claim polymerized reverse micelles containing a cargo with the above properties in a product by process context.

Soane et al. (US 6,884,842, issued 4/26/2005, see whole document, particularly the Abstract; Figs. 12-15, 20a-20c, 21; columns 4-5; columns 10-13; 20; 37-38; 41-43 and 57) recites a process of delivering a cargo (which can be nucleic acids) to cells comprising inserting the cargo into reverse micelles wherein said reverse micelles can comprise a plurality of amphipathic molecules containing reactive functional groups and biologically labile bonds (including disulfide bonds), polymerizing two or more of the amphipathic molecules in the reverse micelles thereby forming a polymerized reverse micelle and using said polymerized reverse micelle to deliver the cargo to cells. Soane et al. also disclose the polymerized reverse micelles so formed by the aforementioned method. With regard to the limitation of claim 16, it is noted that this limitation is not in the form of a method step but rather a description of a property of the biologically labile bond and the reverse micelle formed by the recited method. The wide variety of different reverse micelles disclosed by Soane et al. also comprise biologically labile bonds (which can be ester bonds, amide bonds, bonds on polysaccharides, etc.) between the hydrophobic and hydrophilic portions of the amphipathic molecules making up the reverse micelles and cleavage of these bonds would disrupt the reverse micelle. With regard to the compacted DNA limitation of claim 31, it is noted that applicants indicate in the instant specification, that polymers that increase repulsion between DNA and its surroundings, as well as excluded volume effects, have been shown to compact DNA (See specification, p. 6). Since the reverse micelles disclosed by Soane et al.

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(which can be neutral or anionic) serve to increase repulsion between the DNA and its surroundings, it must be assumed that, absent evidence to the contrary, the DNA contained in said reverse micelles is compacted. Soane et al. therefore teaches the claimed invention.

### **35 USC 112, 1<sup>st</sup> Paragraph Rejections**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants recite a process for delivering a cargo to a cell, comprising inserting said cargo into a reverse micelle comprising a plurality of amphipathic molecules wherein at least one of the molecules contains a biologically labile bond and polymerizing two or more of the amphipathic molecules. In amended Claim 20, applicants recite that the biologically labile bond consists of a silicon-heteroatom bond. The instant application does not provide support for an amphipathic molecule containing a "biologically labile" silicon-heteroatom bond. While the specification recites that one of the bonds in an amphipathic molecule can be a silicon-heteroatom bond and the

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specification describes generation of a amphipathic compound containing a silicon-heteroatom bond (3-dimethylamino-dimethyloctadecyl silyl ether), said specification provides neither explicit or implicit support for the claimed process comprising use of amphipathic molecules containing any "biologically labile" silicon-heteroatom bond.

This is a NEW MATTER rejection.

### **35 USC 112, 2<sup>nd</sup> Paragraph Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is vague in that there is no antecedent basis for the term "the disulfide bond" in the claims from which claim 28 depends.

No Claims are allowed.

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
September 18, 2005

  
DAVID GUZO  
PRIMARY EXAMINER